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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,868	03/29/2006	Tomoko Asakawa	074129-0541	7047

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EXAMINER	
SUTTON, DARRYL C	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
12/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,868	ASAKAWA, TOMOKO	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5 and 8-15* is/are pending in the application.

4a) Of the above claim(s) *13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed 08/26/2010. No new claims have been added.

Applicant's arguments filed 08/26/2010 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahern et al. (Europ. J. of Pharacol., 2000) in view of MacDonald et al. (Diabetes, 2002) and Nauck et al. (Diabetes Care, 1998).

Ahren et al. teach the use of a valine-pyrrolidone, an inhibitor of dipeptidyl dipeptidase IV, DPP-IV, administered to increase GLP-1 levels (page 239, Abstract, page 240, 1st column, 1st paragraph). DPP-IV is the enzyme responsible for the

degradation of GLP-1 (page 239, 2nd column, 1st paragraph). Valine pyrrolidone potentiated plasma levels of GLP-1 and potentiated glucose-stimulated insulin secretion (page 243, 2nd column, 1st paragraph and page 244, 3rd paragraph).

Ahren does not teach a mammal with sulfonylurea secondary failure or testing if said mammal can no longer close an ATP-sensitive K+ channel.

MacDonald et al. teach that GLP-1 enhances insulin secretion through mechanisms involving the regulation of ATP sensitive K+ channels in addition to inducing expansion of insulin secreting β–cell mass. The GLP-1 receptor is expressed in β–cells (Abstract, page S434, 2nd column, 2nd paragraph). The ability for sulfonylureas via ATP sensitive K+ channel inhibition to stimulate insulin secretion decreases over time, i.e. sulfonylurea secondary failure. DPP-IV inhibition is a promising strategy shown to prolong activity of GLP-1 (page S435, 2nd column, "Type 2 diabetes and GLP-1 receptor agonists"). One of the many observed cellular function of GLP-1 is the inhibition of K_{ATP} channels (page S436, “GLP-1 and β–cell KATP channels).

MacDonald et al. do not teach the specific method of treating diabetes with sulfonyl secondary failure or a method of promoting insulin secretion in a diabetic patient in need thereof with sulfonyl urea secondary failure by (a) testing if a mammal or patient can no longer close an ATP-sensitive K+ channel due to stimulation by a sulfonylurea receptor binding compound and (b) administering to said mammal or patient an effective amount of a dipeptidyl dipeptidase IV inhibitor.

Nauck et al. teach that GLP-1 stimulated insulin secretion in mild diabetic patients and in patients who were in poor metabolic control of sulfonylurea treatment, i.e. at the point of sulfonylurea secondary failure (page 1925, 3rd column, 1st paragraph and page 1928, "Conclusion"). A similar glucose threshold for GLP-1 induced insulin secretion is still active in patients with true secondary sulfonylurea secondary failure (page 1929, 2nd column, 1st paragraph).

Nauck et al. do not teach administration of a DPP-IV.

At the time of the invention, it would have been obvious to use the methods and DPP-IV inhibitor of Ahren et al. to treat diabetes with sulfonylurea secondary failure, i.e. the decrease of insulin secretion over time due to use of sulfonylurea compounds, since the compounds inhibit the deactivation of GLP-1 via inhibition of DPP-IV and induce expansion of insulin secreting β–cells which stimulates insulin secretion as taught by MacDonald et al. and since the glucose threshold for insulin secretion is the same for patients with sulfonylurea secondary failure as taught by Nauck et al. It would have been obvious to first test to see if a mammal can no longer close an ATP-sensitive potassium channel, in order to determine whether the sulfonylurea secondary failure is due to the potassium channel being open, resulting in lack of insulin secretion. The administration of the DPP-IV inhibitor would reasonably be expected to increase GLP-1 levels, which in turn inhibits, i.e. closes, the ATP-sensitive potassium channel and leads to insulin secretion.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahern et al., MacDonald et al. and Nauck et al. as applied to claims 5 and 8-12 above, and further in view of Deacon et al (Expert Opin. Investig. Drugs, 2004).

Ahern et al., MacDonald et al. and Nauck et al. are discussed *supra*.

Ahern et al., MacDonald et al. and Nauck et al. do not teach the compound of instant claim 15.

Deacon et al. teach that MK-0431, i.e. the compound on claim 15, is a DPP-IV inhibitor (page 1094, Figure 1, page 1096, 2nd column 3rd paragraph and page 1097, 2nd column, 2nd paragraph).

Deacon et al. do not teach a specific method of treating diabetes with sulfonyl secondary failure or a method of promoting insulin secretion in a diabetic patient in need thereof with sulfonyl urea secondary failure by (a) testing if a mammal or patient can no longer close an ATP-sensitive K+ channel due to stimulation by a sulfonylurea receptor binding compound and (b) administering to said mammal or patient an effective amount of a dipeptidyl dipeptidase IV inhibitor.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Accordingly, it would have been obvious to use the MK-0431 as the DPP-IV inhibitor in the method suggested by combining Ahern et al., MacDonald et al. and Nauck et al.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 8:30AM to 5:00PM EST or on Fr from 8:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

/Darryl C Sutton/
Examiner, Art Unit 1612